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To: **Examiner Ulrike Winkler**
United States Patent Office

5771
272-0912

Fax No.: ~~703-872-9306~~ (571) 273-0912

From: William D. Schmidt, Esq.
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Attorney for Applicants

Date: July 20, 2004

Pages: 3 total number of pages including cover page

Re: U.S. Serial No.: 09/935,966 - Docket 13099US

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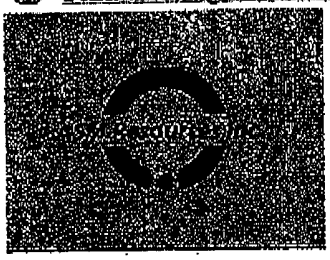

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Control/Tracking Number : ICAAC04-A-1563-ASM
Activity : Abstract
Current Date/Time : 5/5/2004 4:05:12 PM

Therapy of *West Nile* Virus (WNV)Meningoencephalitis with Interferon Alpha-2b

W. WEHBEH[1], C. ROSENBERG [2], J. J. RAHAL [1];
[1]New York Hospital Queens, Flushing, NY, [2]Taro Pharmaceuticals, USA, Inc., Hawthorne, NY.

Background: Interferon α-2b (IFN α-2b) inhibits WNV replication *in vitro*. The potential therapeutic benefit and safety of IFN α-2b was evaluated in patients with WNV meningoencephalitis in a randomized, unblinded, multi-center trial. **Methods:** Patients with clinical and epidemiologic evidence of WNV meningoencephalitis were randomized to IFN α-2b therapy for two weeks (6 million units followed by 3 million units daily), or to an untreated group during the summers of 2002-2003. Treatment was initiated prior to the results of WNV serologic studies. Patients with serologically proven WNV infection and follow-up examination after 3 weeks were included in the outcome analysis. The primary outcome was the change in neurologic function as determined by the N.I.H. Stroke Scale (NIHSS) from randomization to the end of week three. 19 patients were randomized to each group. Among treated patients, 2 were seronegative, 1 was lost to follow up, and 1 died within the first 36 hours. 4 untreated patients were seronegative, 4 were lost to follow up, and three withdrew. Thus, 15 treated and 8 untreated patients were eligible for analysis. 16 patients received IFN α-2b for at least 10 days, and were eligible for toxicity analysis. **Results:** 15 treated and 8 untreated patients were evaluable for efficacy. The mean change in NIHSS from week 1 to week 3 was 9.6 and 3.0 in the treated and untreated groups, respectively (p=0.008 by 2-tailed Fisher's randomization test). Treated patients received IFN α-2b for an average of 12.9 days. Treatment in 5/16 patients (31%) was stopped prior to14 days. The most common adverse events were elevation of serum transaminase and neutropenia. Grade 3 hepato toxicity occurred in 6/16 patients (37.5%), and grade 3 neutropenia in 5/16 patients (31%). These events resolved with drug cessation. **Conclusion:** Treatment of WNV meningoencephalitis with IFN α-2b was safe and had potential benefit. These results support further investigations of early α-IFN therapy for WNV meningoencephalitis.
Author Disclosure Block: W. Wehbeh, None.

Category: (Complete): V
Keywords: (Complete): West Nile virus ; Interferon ; Meningoencephalitis
Additional Information (Complete):
I do NOT have any off-label use(s) to disclose. : True

PTOL-413A (05-03)
Approved for use through xx/xx/xxxx. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 09/935,966 First Named Applicant: James J. Rahal
Examiner: Ulrike Winkler Art Unit: 1648 Status of Application: Pending

Tentative Participants:
(1) William D. Schmidt (2)_____

(3)_____ (4)_____

Proposed Date of Interview: 07-20-04 **Proposed Time:** 4 PM **(AM/PM)**

Type of Interview Requested:
(1) [X] Telephonic (2) [ ] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [ ] YES [ ] NO
If yes, provide brief description:_____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1)_____	_____	_____	[ ]	[ ]	[ ]
(2)_____	_____	_____	[ ]	[ ]	[ ]
(3)_____	_____	_____	[ ]	[ ]	[ ]
(4)_____	_____	_____	[ ]	[ ]	[ ]

[ ] Continuation Sheet Attached

Brief Description of Arguments to be Presented: Clinical human trials

An interview was conducted on the above-identified application on _____.

NOTE:
This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).
This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

William D. Schmidt

(Applicant/Applicant's Representative Signature) (Examiner/SPE Signature)